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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/598,760 | 09/27/2007 | Mike Clifford | CB60772 | 9910 |
| 20462 7590 09/08/2009 SMITHKLINE BEECHAM CORPORATION CORPORATE INTELLECTUAL PROPERTY-US, UW2220 P. O. BOX 1539 KING OF PRUSSIA, PA 19406-0939 | | | | |
| EXAMINER KING, FELICIA C | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1794 | | | | |
| NOTIFICATION DATE | | DELIVERY MODE | | |
| 09/08/2009 | | ELECTRONIC | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary

Application No.

10/598,760

Applicant(s)

CLIFFORD ET AL.

Examiner

FELICIA C. KING

Art Unit

1794

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/11/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date 9/11/06, 10/27/06

DETAILED ACTION

Comment [J1]: Ed Felicia,

Can you make a 102 on drinking juice for claims 1, 2, 5 and 8. You could use a product sheet for Cranberry juice as a 102 and say that it is inherent.

Information Disclosure Statement

1. The listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I, states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(c). See MPEP § 609.05(a).
2. The information disclosure statement filed 9/11/06 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).\

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 10 refer to a series of berries that are claimed as “prebiotics”. However this is inconsistent with the specification which describes the berries as having a “prebiotic effect”. It is unclear what the applicant is trying to claim since the specification appears to create a distinction between traditional prebiotics and berries having a “prebiotic effect”[pg 2, lines 28-31, pg. 3 27-34].

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2, 4, 5, 9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by

Kontiokari et al. (BMJ Vol 322 June 30, 2001 Applicant’s NPL).

7. **Regarding Claims 1, 2, 4, 5, 9, and 10:** Kontiokari discloses administering (by drinking) cranberry juice (liquid, beverage) to women [pg 1]. Although Kontiokari does not explicitly state the cranberry as a prebiotic, because Kontiokari discloses every aspect of the instant claim it is anticipated that the cranberry juice would act as a prebiotic upon administering it to a human. Applicant appears to attribute the prebiotic affect to the administration of the juice and does not teach adding any prebiotic materials to the juice itself (see page 3, lines 27-30 of instant specification), therefore the prebiotic characteristics are considered to be inherent to the juice itself. Therefore with the inherent characteristics, at least some reduction in harmful bacteria would also be inherent.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1794

(g) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1, 2, 4-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castleberry (US 6,020,016) in view of De Jong et al. (US 6,783,780) and Leahy et al. (2002 Pharmaceutical Biology Vol. 40 Supplement pg 504-54).

Regarding Claims 1, 2, 4, 5, and 9: Castleberry discloses a liquid nutritional beverage containing single juice or juice blends made of the berries, black currant, blackberry, blueberry, cranberry, redcurrant, cherry, raspberry plum, grape or pomegranate [col. 3, lines 31-36, col. 4, lines

54-67; col. 5, lines 1-5] in a juice form that is not from concentrate and not watered down [col. 7, lines 5-15; col. 9, claim 11] but does not disclose promoting the growth of beneficial bacteria or where the berries are prebiotics. However, De Jong discloses a digestive health promoting composition that contains non-digestible oligosaccharides which are prebiotics (which are known to promote growth of beneficial bacteria, probiotics) [col. 1, lines 46-59] and can be placed in fruit drinks [col. 4, lines 22-26]. Further however, Leahy discloses that cranberries have been shown to have a prebiotic effect in the gastrointestinal tract [pg.53, "Summary of conclusions from the latest studies"].

At the time of the invention it would have been obvious to one of ordinary skill in the art having the teachings of Castleberry, De Jong and Leahy to modify the fruit juice of Castleberry to include prebiotics in order to promote health gut function. Further, it would have been obvious to one of ordinary skill in the art that the inclusion of at least cranberries in a juice beverage would have promoted a prebiotic effect.

Regarding Claims 6 and 7: Castleberry discloses a nutritional beverage as discussed above and further discloses that the beverage can be in the form of a beverage concentrate [col. 3, lines 21-24; col. 6, lines 57-59] and where the products contain 1-20% fruit [col. 7, lines 5-15][col. 9, claim 11]. De Jong and Leahy disclose as discussed above.

Regarding Claim 8: Castleberry discloses a nutritional liquid beverage as discussed above but does not disclose including probiotics. However, De Jong discloses adding probiotics to a beverage [col. 1, lines 46-59; col.4, lines 22-26]. Leahy discloses cranberries as prebiotics as discussed above.

At the time of the invention it would have been obvious to one of ordinary skill in the art having the teachings of Castleberry, De Jong and Leahy to incorporate probiotics into the beverage

since the purpose of prebiotics is to provide nourishment for probiotics thereby promoting their growth.

12. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Castleberry (US 6,020,016) and Puupponen-Pimia et al. (2004 Bioscience Microflora Vol. 23 (2), 67-80).

Regarding Claim 10: Castleberry discloses a nutritional beverage as discussed above but does not disclose where the composition is capable of reducing the amount of harmful bacteria. However, Puupponen-Pimia discloses that berries such as blackcurrants and cranberries are high in phenolic compounds [pg 68, 2nd full para] and that berry phenolics inhibited the growth of intestinal pathogens [pg 74, last para].

At the time of the invention it would have been obvious to one of ordinary skill in the art having the teachings of Castleberry and Puupponen-Pimia before him or her to utilize the berries of Castleberry in order to provide very well known health benefits found in phenolic compounds but also the antimicrobial benefits as described by Puupponen-Pimia.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Sobol et al. (US 6,953,574) discloses using pomegranate, cranberry, and black currants in a fermented medium containing probiotics in order to promote good health and particularly names colon health.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FELICIA C. KING whose telephone number is (571)270-3733. The

examiner can normally be reached on Mon- Thu 7:30 a.m. - 5:00 p.m.; Fri 7:30 a.m. - 4:00 p.m.
alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer McNeil can be reached on 571-272-1540. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Ruthkosky/
Supervisory Patent Examiner, Art Unit 1794

/F. K./
Examiner, Art Unit 1794